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# Societal CDMO Signs Three-Year Manufacturing and Supply Agreement With InfectoPharm for Ritalin LA® in Europe

## Agreement Establishes Societal as Exclusive Supplier in Europe Through 2023

SAN DIEGO, and GAINESVILLE, Ga., May 05, 2022 (GLOBE NEWSWIRE) -- Societal CDMO, Inc. ("Societal CDMO" or "Societal"; NASD: [SCTL](#)), a contract development and manufacturing organization (CDMO) dedicated to solving complex formulation and manufacturing challenges primarily in small molecule therapeutic development, today announced that it has entered into a three-year manufacturing and supply agreement with InfectoPharm for Ritalin LA® capsules (methylphenidate hydrochloride extended-release capsules) in Europe. The new agreement, which is effective immediately and runs through April 2025, establishes Societal as the exclusive supplier of Ritalin LA capsules for the European market through 2023.

Societal has a long-standing relationship with Novartis and has served as the company's exclusive global supplier of Ritalin LA and Focalin XR® capsules for approximately 20 years. Novartis recently divested European rights to Ritalin LA capsules to InfectoPharm and this newly signed agreement serves to maintain Societal's role as the exclusive supplier of Ritalin LA capsules in Europe. Societal's exclusive Manufacturing and Supply Agreement with Novartis for Ritalin LA and Focalin XR capsules for the remainder of the world remains unchanged and continues through 2023. Revenue from Novartis in 2021 represented approximately 24% of Societal's overall revenue and the Company estimates that the Ritalin LA capsules sub-component for the European market represented approximately 30% of its revenues from Novartis.

"Societal has a long history and know-how with Ritalin, dating back to the company's innovative formulation work that allowed for the creation of an extended-release version of the product. Over the years, we've enjoyed an excellent relationship with Novartis while serving as the exclusive global supplier of Ritalin LA capsules," said David Enloe, chief executive officer of Societal CDMO. "We now look forward to delivering the same high quality supply and manufacturing services to the InfectoPharm team to support the company's commercial efforts for the product in the European market."

"This is an important agreement for InfectoPharm as it ensures continuity in the supply chain of Ritalin LA as we work to meet the needs of patients and physicians within the European market. We are particularly pleased to align with a trusted and reliable partner such as Societal CDMO, which achieved on time and in full delivery for the Ritalin LA product in in the past," stated Philipp Zöller, managing director, InfectoPharm.

Ritalin LA is indicated for the treatment of attention deficit hyperactivity disorder (ADHD). The product is an extended-release formulation of methylphenidate hydrochloride with a bi-modal release profile using the proprietary SODAS® (Spheroidal Oral Drug Absorption System) technology. Each bead-filled Ritalin LA capsule contains half the dose as immediate-release beads and half as enteric-coated, delayed-release beads, thus providing an immediate release of methylphenidate and a second delayed release of methylphenidate.

### **About Societal CDMO**

Societal CDMO (NASDAQ: [SCTL](#)) is a bi-coastal contract development and manufacturing organization (CDMO) with capabilities spanning pre-Investigational New Drug (IND) development to commercial manufacturing and packaging for a wide range of therapeutic dosage forms with a primary focus in the area of small molecules. With an expertise in solving complex manufacturing problems, Societal CDMO is a leading CDMO providing therapeutic development, end-to-end regulatory support, clinical and commercial manufacturing, aseptic fill/finish, lyophilization, packaging and logistics services to the global pharmaceutical market.

In addition to our experience in handling DEA controlled substances and developing and manufacturing modified-release dosage forms, Societal CDMO has the expertise to deliver on our clients' pharmaceutical development and manufacturing projects, regardless of complexity level. We do all of this in our best-in-class facilities, which total 145,000 square feet, in Gainesville, Georgia and San Diego, California.

Societal CDMO: Bringing Science to Society. For more information about Societal CDMO's customer solutions, visit [societalcdmo.com](http://societalcdmo.com).

### **Forward-Looking Statements**

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "anticipate", "believe", "could", "estimate", "upcoming", "expect", "intend", "may", "plan", "predict", "project", "will" and similar terms and phrases may be used to identify forward-looking statements in this press release. Our operations involve risks and uncertainties, many of which are outside our control, and any one of which, or a combination of which, could materially affect our results of operations and whether the forward-looking statements ultimately prove to be correct. Factors that could cause the company's actual outcomes to differ materially from those expressed in or underlying these forward-looking statements include risks and uncertainties associated with current and future economic conditions, including any adverse impact on customer ordering patterns or inventory rebalancing or disruption in raw materials or supply chain; demand for the company's services, which depends in part on customers' research and development and the clinical plans and market success of their products; customers' changing inventory requirements and manufacturing plans; customers and prospective customers decisions to move forward with the company's manufacturing services; the average profitability, or mix, of the products the company manufactures; the company's ability to enhance existing or introduce new services in a timely manner; fluctuations in the costs, availability, and suitability of the components of the products the company manufactures, including active pharmaceutical ingredients, excipients, purchased components and raw materials, or the company's customers facing increasing or new competition. These forward-looking statements should

be considered together with the risks and uncertainties that may affect our business and future results presented herein along with those risks and uncertainties discussed in our filings with the Securities and Exchange Commission at [www.sec.gov](http://www.sec.gov). These forward-looking statements are based on information currently available to us, and we assume no obligation to update any forward-looking statements except as required by applicable law.

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